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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,969	02/16/2001	Bernard Charles Sherman	PT-1858001	3343

23607 7590 10/22/2002

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1614

DATE MAILED: 10/22/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/783,969

Applicant(s)

SHERMAN, BERNARD CHARLES

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 15-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/403,660.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of Application***

1. Acknowledgement is made of applicant's amendment filed on September 27, 2002. The request for withdrawal of the finality is accepted and the status of previous office action should be corrected to the non-final rejection. Amendment and the terminal disclaimer has entered properly and this office action supercedes any previous office action.
2. Claims 1 and 15-23 are pending and presented for the prosecution the merit.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauer et al (US 5,342,625).

US'625 (Hauer et al) teaches a pharmaceutical composition comprising a cyclosporin as an active agent in the form of "microemulsion pre-concentrate" and "emulsion pre-concentrate", see abstract. At column 6, lines 10-65, US'625 teaches that the microemulsion pre-concentrate composition having a size of droplet less than 2000A, comprises cyclosporin an an active agent, hydrophilic phase, a lipophilic phase and surfactant(s). The patented composition comprises: (1) a hydrophilic phase that is designated to "1.1 or 1.2", comprising hydrophilic organic solvent such as propylene

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glycol, certain ethers (e.g. TRANSCUTOL™ or COLYCOFUROL™), lower alkanols, or mixture thereof,(see column 7, lines 19-column 8, lines 55); (2) a lipophilic phase that is designated to "2",comprising fatty acid triglycerides(e.g. MIGLYOL™), see columns 8-9; (3) the surfactant component that is designated to "3.1.1-3.1.9" comprising hydrophilic surfactants(e.g. CREMOPHOR™) and lipohydrophilic surfactants(e.g.MYVACET™ - ("3.2.5") ), mixtures thereof, see column 9, line 40- column 12, lines 15.

As to claim 1 regarding an emulsion preconcentrate, US'625 exemplifies a composition ("C") in the form of emulsion pre-concentrate comprising cyclosporin(active agent); a MYVACET™ (co-solvent/lipophilic surfactant); a hydrophilic solvent; and additional surfactant and co-solvent, see column 14, lines 40-64. All the required elements are taught by this reference. It is noted that commercially available MYVACET™ is fully acetylated monoglyceride having a minimum acetylation of 96%, see instant specification page 7(also admitted by the applicant).

As to claim 15 regarding a micro emulsion preconcentrate, US'625 exemplifies a composition ("A" or "B") comprising cyclosporin; mixtures of surfactants including MYVACET™. Thus all the required elements are met by the reference, see column12, lines 15-48.

Although applicant's claims are not contemplated in the exemplified patented composition, it would have been obvious to any ordinary skill in the art to modify Hauer's teaching to formulate the claimed composition because all the claimed elements are taught by the cited reference. For instance, the limitation recited in claims

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18-19 and 22-23 (e.g. hydrogenated vegetable oils and polyoxyethylene-sorbitan-fatty ester) are taught in columns 9-10, designated to "3.1.1-3.1.2".

As to claim 16, Hauer teaches that microemulsion preconcentrate A composition also include a first surfactant and mixture of surfactants(one or more secondary surfactants) wherein Hauer recognized MYVACET as one of his preferred lipophilic surfactant/co-solvent to make the said A composition, see column 12, lines 15-50, especially lines 35-36.

One would have been motivated to make such composition in the form of microemulsion preconcentrate or emulsion preconcentrate having cyclosporin, hydrophilic solvent, lipophilic solvent and mixture of surfactant to enhance the quality of of the said composition because a combination of the two or more may be better than either alone to enable higher concentration of the drug and adequate ease of dispersion, especially due to their dual functionality which acts as both surfactant and solvent as recognized by the cited patent. Thus one would have make such modification using the same ingredients suggested by Hauer with reasonable expectation of success.

One would have been motivated to combine these references and make the modification because they are drawn to the same technical field(constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns with. MPEP 2141.01(a).

### ***Conclusion***

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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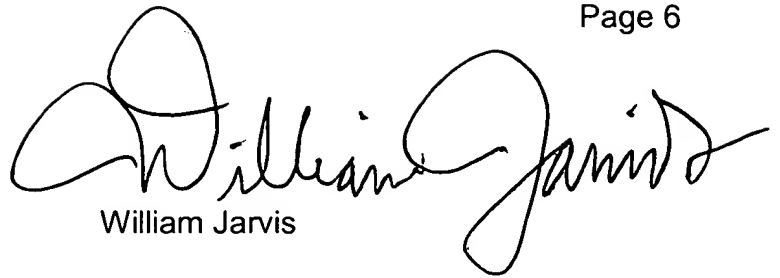
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Vickie Kim,

Patent examiner

October 18, 2002

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A handwritten signature in black ink, reading "William Jarvis". The signature is fluid and cursive, with the first name "William" and last name "Jarvis" clearly distinguishable.

William Jarvis

Primary Patent examiner